Dear Owner/Operator:

The Food Safety and Inspection System (FSIS) is providing general notification to identification warehouses that subdivide bulk units into smaller units (breaking bulk) that the Agency will not provide identification service under 9 CFR 350.3 for beef products that bear a disclaimer statement (e.g., "not tested for *E. coli* O157:H7") or instructional statement (e.g., "for cooking only") concerning *Escherichia coli* (*E. coli*) O157:H7.

When FSIS approves the use of such statements, FSIS specifies that they can only be used on products destined for official establishments. FSIS cannot allow labels to be applied in an identification warehouse in a manner that is not consistent with their approval.

However, an establishment that places an instructional or disclaimer statement that addresses *E. coli* O157:H7 on raw beef products may send such product to a warehouse if the establishment ensures that <u>all</u> of the following conditions will be met:

- 1) The product will not be broken down into smaller units or repackaged at the warehouse;
- 2) The warehouse will hold the product under appropriate conditions so that it will not be rendered injurious to health or otherwise rendered adulterated, including ensuring that the product will not be held at temperatures that would allow *E. coli* O157:H7 or other pathogens of public health concern to multiply;
- 3) The warehouse will ship the product bearing the instructional or disclaimer statement only to an official establishment that has an appropriate production process; and
- 4) The producing establishment has a means of documenting that a second official establishment ultimately received the product and processed the product appropriately.

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The Agency notes that identification warehouses are not subject to the Sanitation Standard Operating Procedures (SSOPs) regulatory requirements, 9 CFR 416.11-17. The potential for cross contamination of product with *E. coli* O157:H7 exists in the absence of SSOPs. Therefore, inspection program personnel will detain affected product if breaking bulk or repackaging of product bearing this type of statement is observed at an identification warehouse. Moreover, failure of an identification warehouse to adhere to the provisions of its application for service could result in that service being withdrawn.

Sincerely,

Philip S. Derfler

Assistant Administrator

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Office of Policy and Program Development